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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/934,356 | 08/21/2001 | Dale E. Koop | CTC-401 | 7685 |

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EXAMINER

FARAH, AHMED M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3739

DATE MAILED: 05/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/934,356

Applicant(s)

Dale E. Koop

Examiner

A. Farah

Art Unit

3739



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 31, 2002; and Feb 19, 2003
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3, 5, 6 6) ☐ Other: _____

Art Unit: 3739

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

2. Claims 1-3 and 8-10 are again rejected under 35 U.S.C. 102(e) as being anticipated by O'Donnell, Jr. U.S. Patent 6,106,514.

O'Donnell, Jr. discloses apparatus and method for treating subsurface layer of skin, the method comprising the steps of:

applying anti-inflammatory, anti-oxidant (wound healing) pharmaceutical agent to the skin (Col. 3, lines 21-26); and

irradiating the skin with laser energy sufficient to cause stimulation of collagen remodeling for the purpose of effecting the tightening of the skin and reducing wrinkles without significantly altering the epidermis (see claims 1-3).

As to claim 3, O'Donnell, Jr. applies mechanical energy to the skin tissue (Col. 6, lines 6-10).

Art Unit: 3739

As to claim 8, his treatment reduces wrinkles. Therefore, since wrinkles result from photodamaged and/or aging skin, he provides the claimed method step.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 4-6 and 11 are again rejected under 35 U.S.C. 103(a) as being unpatentable over O'Donnell, Jr. in view of Purchio et al. U.S. Patent 5,599,788.

Although O'Donnell, Jr., described above, discloses pharmaceutical agent to enhance the treatment, he does not teach the use of growth factor such as H3 protein to promote the healing process.

However, Purchio et al. disclose a method of producing recombinant transforming growth factor β -induced H3 protein and its use to accelerate wound healing. They further teach that H3 protein may be combined with conventional chemotherapy and radiation treatment to increase the over all treatment efficiency (Col. 4, lines 58-60).

Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify O'Donnell, Jr. and apply a growth factor such as H3 protein to

Art Unit: 3739

the skin as taught by Purchio et al. in order to accelerate the wound healing and to enhance the over all treatment efficiency.

As to claim 6 of the instant application, claim 3 of O'Donnell, Jr. teaches the claimed limitation.

5. Claim 7 is again rejected under 35 U.S.C. 103(a) as being unpatentable over Tankovich et al. U.S. Patent 5,817,089 in view of Purchio et al. ('788).

Tankovich et al. disclose phototherapy treatment methods for the reduction and removal of unwanted hair and the mitigation of skin conditions such as acne and seborrhea. However, they do not apply wound healing promoter composition to the skin to enhance the healing process.

Purchio et al., described above, teach the use of a wound healing protein, which may be combined with conventional chemotherapy and radiation treatment to increase the over all treatment efficiency. Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify the invention of Tankovich et al. with Purchio et al. to apply a wound healing protein to the skin being treated so as to enhance the wound healing process and improve the over all treatment efficiency.

Response to Arguments

6. Applicant's arguments filed December 31, 2002 have been fully considered but they are not persuasive. The applicant makes the following arguments:

Art Unit: 3739

A) U.S. Patent 6,106,515 to O'Donnell, Jr. (hereafter referred as '515), fails to disclose a "wound healing composition" as recited in claim 1 and disclosed in his application. The applicant further argues that a wound healing composition as defined by the his specification includes "a composition that amplifies the natural stimulation of growth or collagenesis caused by a wound." He further asserts that "remodeling is further enhanced by the use of a transforming growth factor which accelerates the wound healing."

In response to this argument:

(i) applicant's claim 1 recites the limitation "applying a wound healing composition to the skin." This is a broad limitation and therefore treated as broadly as claimed.

(ii) U.S. Patent '515 teaches a **photocoagulation** method of the dermis for **reducing wrinkles**, the method comprising the steps of **irradiating the skin** with laser energy and topically applying **pharmaceutical agent to the skin** to promote healing (Col. 3, lines 52-61).

(iii) the term **photocoagulation** is defined as a 'surgical coagulation of tissue by means of intense light energy, such as a laser beam, performed to destroy abnormal tissues or to form **adhesive scar**.' Furthermore, the prior art teaches that 'the mechanism of wrinkle reduction is based upon the reversal of the net collagen reduction stimulated by solar exposure. The net gain of collagen in the papillary dermis results from a biological response to iatrogenic injury, whether by chemical, mechanical or laser-induced trauma. The biological response is in the form of the complex sequence of events incorporated in the wound repair process culminating in, among other factors, histological, immunohistological and in situ hybridization evidence of new

Art Unit: 3739

collagen synthesis in the papillary dermis.' Therefore, the Examiner's position is that wound healing is inherent to O'Donnell's method for reducing wrinkles.

B) As to claim 11, the applicant argues that a motivation to combine the teachings of the references is not immediately apparent and, therefore, the Office Action (OA) fails to establish a prima facie case of obviousness.

In response to this argument, the OA clearly states the motivation for combining the references, viz. *'apply a growth factor such as H3 protein to the skin, as taught by Purchio et al., accelerates the wound healing and enhances the over all treatment efficiency.'*

C) As to claim 7, the applicant argues that U.S. Patent 5,599,788 to Purchio (hereafter referred as '788) is non-analogous art and "is not in the field of endeavor of the present invention or even reasonably pertinent to the problem being solved."

In response to this argument, U.S. Patent '788. teaches the use of a wound healing protein, which may be combined with conventional chemotherapy and radiation treatment to increase the over all treatment efficiency (see Col. 4, lines 58-60).

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

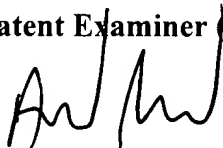
Art Unit: 3739

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

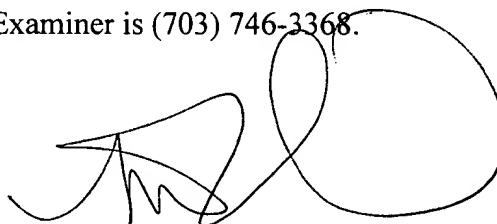
Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. Farah whose telephone number is (703) 305-5787. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Linda Dvorak, can be reached on (703) 308-0994. The fax number for the Examiner is (703) 746-3368.

A. M. Farah

Patent Examiner (Art Unit 3739)



April 29, 2003



Linda C. M. Dvorak

Supervisory Patent Examiner